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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,221	12/21/2001	Raghuram Kalluri	2312/2082B	3472

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,221	KALLURI, RAGHURAM	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *18 October 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-107* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-42, 51, 54, , drawn to an isolated fragment of SEQ ID NO: 10, having ability to inhibit tumor growth, inhibit angiogenesis or inhibit protein synthesis in endothelial cells, classified in Class 530, subclasses 300 and 324.

II. Claims 43-47, drawn to a method for inhibiting tumor growth in mammalian tissue with a fragment of SEQ ID NO:10, classified in Class 514, subclass 12.

III. Claim 48, drawn to a method for inhibiting angiogenic activity in mammalian tissue with a fragment of SEQ ID NO:10, classified in Class 514, subclass 12.

IV. Claims 49-50, 52-53 and 55-56, drawn to a method for inhibiting protein synthesis in one or more mammalian cells with a fragment of SEQ ID NO:10, classified in Class 514, subclass 12.

V. Claims 57-101 and 105-107, drawn to a peptide of the formula: $R^1X^1LFX^2NVNX^3VXNFR^2$ (SEQ ID NO: 45), classified in Class 530, subclasses 300 and 324.

VI. Claim 102, drawn to a method for inhibiting tumor growth in mammalian tissue comprising contacting the tissue with a peptide of the formula: $R^1X^1LFX^2NVNX^3VXNFR^2$ (SEQ ID NO: 45), classified in Class 514, subclass 12.

VII. Claim 103, drawn to a method for inhibiting angiogenic activity in mammalian tissue comprising contacting the tissue with a peptide of the formula: $R^1X^1LFX^2NVNX^3VXNFR^2$ (SEQ ID NO: 45), classified in Class 514, subclass 12.

VIII. Claim 104, drawn to a method for inhibiting protein synthesis in mammalian tissue comprising contacting the tissue with a peptide of the formula: $R^1X^1LFX^2NVNX^3VXNFR^2$ (SEQ ID NO: 45), classified in Class 514, subclass 12.

2. Groups II-IV and VI-VIII are different methods. A method of inhibiting tumors, a method of inhibiting angiogenic activity, and a method of protein syntheis differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

3. Groups (I and II-IV) and (V and VI-VIII) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the fragments and peptides of Groups I and V, respectively, can be used to make antibodies, in addition to the recited methods of inhibition.

4. These inventions are distinct for the reasons given above. Even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

Species Election

5. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If Group I is elected, applicant is required to elect a specific fragment such as a) SEQ ID NO:37, b) SEQ ID NO: 38, c) SEQ ID NO:39, d) SEQ ID NO:40, e) SEQ ID NO: 41, or SEQ ID NO: 32. These are distinct species because their structures, physiochemical properties, and modes of action are different which, in turn, address different therapeutic endpoints, a person of ordinary skill in the art would not envision one in view of the other.

B. If Group II or III is elected, applicant is required to elect a specific fragment such as a) SEQ ID NO:10, b) amino acid 1-124 of SEQ ID NO:10, c) SEQ ID NO:20, d) SEQ ID NO: 21, e) SEQ ID NO: 22, SEQ ID NO: 23, f) SEQ ID NO: 25, g) SEQ ID NO: 26, h) SEQ ID NO: 29, i) SEQ ID NO:30, j) SEQ ID NO: 33, k) SEQ ID NO: 34, l) SEQ ID NO: 37, m) SEQ ID NO: 38, n) SEQ ID NO: 39, o) SEQ ID NO: 40, p) SEQ ID NO: 41, or q) SEQ ID NO: 42. These are distinct species because their structures, physiochemical properties and modes of action are different which, in turn, address different therapeutic endpoints; a person of ordinary skill in the art would not envision one in view of the other.

C. If Group IV is elected, applicant is required to elect a specific fragment, wherein the fragment is a) SEQ ID NO:10, b) amino acid 1-124 of SEQ ID NO:10, c) SEQ ID NO:20, d) SEQ ID NO: 21, e) SEQ ID NO: 22, SEQ ID NO: 23, f) SEQ ID NO: 25, g) SEQ ID NO: 26, h) SEQ ID NO: 29, i) SEQ ID NO:30, j) SEQ ID NO: 33, k) SEQ ID NO: 34, l) SEQ ID NO: 37, m) SEQ ID NO: 38, n) SEQ ID NO: 39, o) SEQ ID NO: 40, p) SEQ ID NO: 41, q) SEQ ID NO: 42, r) SEQ ID NO: 2, or s) SEQ ID NO: 6. These are distinct species because their structures, physiochemical properties and modes of action are different which, in turn, address different therapeutic endpoints; a person of ordinary skill in the art would not envision one in view of the other.

D. If anyone of Groups V-VIII is elected, applicant is required to elect a single specific peptide, wherein R^1 is a) P, b) MP, c) TMP, d) SEQ ID NO: 46, e) SEQ ID NO: 47, SEQ ID NO: 48, f) SEQ ID NO: 49, g) SEQ ID NO: 50, h) SEQ ID NO: 51 or i) a conservative variant of one of (a)-(i); and wherein R^2 is a) A, b) AS, c) ASR, d) SEQ ID NO: 52, e) SEQ ID NO: 53, f) SEQ ID NO: 54, g) SEQ ID NO: 55, h) SEQ ID NO: 56, i) SEQ ID NO: 57 or j) SEQ ID NO: 58 or k) a conservative variant of one of (a)-(j);. These are distinct species because their structures, physiochemical properties and modes of action are different which, in turn, address different therapeutic endpoints; a person of ordinary skill in the art would not envision one in view of the other.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

6. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

9. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.
12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 872-9307.

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Patent Examiner
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November 28, 2003

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